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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,716	10/31/2003	H. William Bosch	029318-0977	8372

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EXAMINER	
JEAN-LOUIS, SAMIRA JM	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
12/15/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/697,716	**Applicant(s)** BOSCH ET AL.	
	Examiner SAMIRA JEAN-LOUIS	**Art Unit** 1617	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 20 November 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): Obviousness Double Patenting Rejection.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: _____.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617

The Examiner respectfully points out that in the response to Amendment in the Final rejection dated 09/16/08, the rejection under 35 U.S.C.102 (b) was withdrawn. Subsequently, a rejection of claims 1-5, 7, 9-14, 18-21, 28-41, and 43-47 was made under 35 U.S.C.103 (a). Furthermore, given that the co-pending application 10/683,154 has been abandoned, the ODP rejection in the Final Office Action dated 09/16/08 is hereby withdrawn.

Applicant's traversal of the 35 U.S.C.103 (a) rejection of claims 1-5, 7, 9-14, 18-21, 28-41, and 43-47 over Krause in view Radhakrishnan has been fully considered but is not found persuasive. Given that Krause teaches triamcinalone that are encapsulated within PLA particles and given that Krasue also teach PLA particle sizes of less than 1 micron, the Examiner contends that one of ordinary skill in the art would have concluded that the triamcinalone cannot be bigger than the capsule that contains it. As a result, one of ordinary skill in the art would have envisaged that the PLA encapsulated triamcinalone particles would necessarily have to be of a size less than 1 micron. As for applicant's arguments that Krause does not specify the effective triamcinalone particle size, such arguments are again not persuasive as Krause clearly teaches that a suspension of the nanoparticles (PLA encapsulated triamcinalone) was maintained for each distribution wherein the size of the PLA particles were from 500 nm, 476 nm and 710 nm; all of which are under 1 micron (see pg. 147, Size distribution and table 1). Thus, Krause does indeed render obvious applicant's invention.

Applicant's traversal of the PLA as a stabilizer or a capsule has been fully considered but is not found persuasive. The Examiner reiterates the fact that the drug is embedded in the center of the PLA sphere which necessarily mean that the PLA particle is adsorbed unto (i.e. on top of) the triamcinalone and this reads on applicant's limitation. Moreover, the Examiner respecfully points out that the PLA can also serve more than one purpose in a solution. In this instance, it can prevent agglomeration of particles due to encapsulation of the drug and second, as a stabilizer that allows the small triamcinalone particles to disperse effectively. Additionally, Krause teaches the addition of other stabilizers to his composition such as gelatin for emulsification purposes (see pg. 147, Preparation of PLA particles) thereby suggesting to one of ordinary skill in the art to add gelatin if an emulsified composition is desired. Thus, given that applicant did not define a stabilizer as solely a surfactant, the Examiner contends that anything that stabilizes the compound such as PLA can necessarily be viewed as a stablilizer. Thus, for the foregoing reasons, the Examiner contends that Krause does indeed render obvious applicant's invention.

Appplicant's traversal of Unger has again been fully considered but is not found persuasive. Unger was provided to demonstrate that encapsulated drugs including triamcinalone, aspirin, and emulsifiers can all be encapsulated and administered topically. Therefore, Unger does indeed render obvious applicant's claims 6, 17, and 22. For the foregoing reasons, the Examiner contends that the 103 (a) rejections over Krause in view of Radhakrishan and in further view of Unger were indeed proper and are MAINTAINED.